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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,826	11/30/2001	Asser Sloth Andersen	6210.200-US	7631

23650 7590 06/17/2004

NOVO NORDISK PHARMACEUTICALS, INC
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PRINCETON, NY 08540

EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/002,826

Applicant(s)

ANDERSEN ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,8. 6) ☐ Other:

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Detailed Action

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenkrantz et al.

Applicants claim a polynucleotide construct comprising a polynucleotide sequence encoding a non-bacterial polypeptide and a DNA sequence encoding a CIT1 yeast promoter or a functional part or variant thereof or a CIT1 promoter consisting of all or part of SEQ ID NO:1 or all or portions of specific regions of SEQ ID NO:1 and optionally a leader sequence for secretion of the expressed polypeptide. Applicants also claim a yeast expression vector comprising the aforementioned components and a possible transcription termination sequence.

Rosenkrantz et al. (Curr. Genet., 1994, Vol. 25, pp. 1851-95, see whole article, particularly p. 186, "Materials and Methods" section, paragraph entitled "Construction of CIT1-lacZ gene fusions" and Fig. 6) recites a polynucleotide construct encoding the *S. cerevisiae* citrate synthase (CIT1) polypeptide (a non-bacterial polypeptide) and a DNA encoding a CIT1 promoter consisting of part of SEQ ID.NO:1 (See Fig. 6). It is noted that the yeast citrate

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synthase polypeptide naturally possesses a leader sequence for secretion and the CIT1 gene cloned by Rosenkrantz et al. (like essentially all genes) naturally has a transcription termination sequence. Rosenkrantz et al. also recites a yeast shuttle vector (pFL1) comprising the CIT1 gene, this vector can also be considered an expression vector since the CIT1 gene can be expressed from this vector. Rosenkrantz et al. therefore teaches the claimed invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (and dependent claims) is vague in that there is no antecedent basis for the term "the desired polypeptide".

Claim 6 is vague in that there is no antecedent basis for the term "the expressed polypeptide" in claim 1.

Claim 17 is vague in the recitation of the term "...a possible transcription terminator sequence." It is unclear how a "possible" transcription terminator differs from an **actual** transcription terminator sequence. It is unclear under what circumstances a "possible"

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transcription terminator sequence becomes a real transcription terminator and under what conditions it does not.

Claims 18-19 are vague in the recitation of "Yeast cells" transformed with the recited polynucleotides or vectors. Recitation of multiple "yeast cells" renders the claim vague because it is unclear whether the transformed cells are part of a monoculture of cells from a single yeast species or a mixed culture of transformed cells from different species of yeast, etc. The metes and bounds of the claimed subject matter are therefore unclear. Redrafting the claims to read on "A yeast cell transformed..." would be remedial.

Claim 19 is vague in that there is no antecedent basis in claim 18 (or claims from which it depends) for the term "a vector according to claim 18".

Claims 1-10 are free of the prior art because the prior art does not teach the claimed process of making a heterologous non-bacterial protein by culturing a yeast cell comprising an expression construct containing the CIT1 promoter operably linked to the non-bacterial polypeptide coding sequence. The closest prior art (Rosenkrantz et al., cited above) teaches generation of expression constructs designed to determine the regions of the yeast CIT1 promoter necessary for glucose repressed and de-repressed expression, said constructs used the bacterial lacZ gene as a marker. Claims 18-19 are free of the art because said art does not teach yeast cells

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containing a DNA comprising the recited components of claims 11 or 18.

It is also noted that applicants define the "CIT1" yeast promoter as the natural or wild-type promoter sequence (from *S. cerevisiae*) disclosed by Rosenkrantz et al. (Curr. Genet. 1994, 25, pp. 185-195) and Rosenkrantz et al. (Molecular Microbiology, 1994, 13(1), 119-131) or its complementary sequence and applicants define "functional part or variant of the CIT1 promoter" as modified forms of the natural CIT1 promoter as long as promoter activity is not adversely affected (specification, p. 3). It is noted that the CIT1 promoter has been extensively studied with regard to functional motifs, motifs necessary for glucose repressed and de-repressed expression, HAP2,3,4-binding sites, etc. Applicants therefore provide a correlation between the structure of the promoter and its function, so that the skilled artisan would be able to envision functional parts or variants of the recited sequence.

The Chevallier et al. (Gene, 1980, Vol. 11, pp. 11-19) reference is cited to show the characteristics of the pFL1 plasmid vector.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (703) 308-1906.

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The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
September 2, 2003

DAVID GUZO
PRIMARY EXAMINER
